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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,694	12/31/2001	Jeff T. Hutchins	07083.0008U5	1998

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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/038,694

Applicant(s)

HUTCHINS ET AL.

Examiner

Sheridan K Snedden

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-19 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. This Office Action is in response to Paper filed 8/24/2004. Claims 1-8 and 28-80 have been canceled. Applicant's amendment of claims 9, 11 is acknowledged. Claims 9-19 are under examination.

Withdrawal of Objections and Rejections

2. The objections and/or rejections not explicitly restated or stated below are withdrawn.

Maintained Objections and Rejections

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg (US 4,894,440) in view of Warmen *et al.* (US 2002/0137894 A1), Flannery *et al.* (IDS) and Chubinskaya *et al.* (US 2002/0052358).

Rosenberg teaches MSF purified to homogeneity (7.5.times.10.sup.5 -fold) from serum-free conditioned medium obtained from cultured human embryonic kidney (HEK) cells. As a

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matter of fact, MSF is referenced in the art as SZP and proteoglycan 4 (see for example, Ikegawa *et al.* (IDS)).

Rosenburg does not expressly teach the use of chondrocytes (regarding claims 9 and 10).

Warmen *et al.* teach CACP, which is the same as MSF (see section [0088]). "Superficial zone protein" (SZP) is described as the bovine ortholog of CACP (see section [0088]). Figure 3 shows that chondrocytes make CACP, suggesting that bovine chondrocytes would make SZP.

Flannery *et al.* teach that SZP may be purified from bovine chondrocytes cultured in agarose in 5% solution of serum. The cells were cultured, the media harvested and the SZP was purified (see page 536, last paragraph).

Chubinskaya *et al.* teach mammalian chondrocytes, which can be immortalized (e.g., chondrosarcoma cells) or non-immortalized (see section [0085]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use immortalized or non-immortalized chondrocytes in the method of Rosenberg *et al.* A person of ordinary skill would have been motivated to purify SZP from chondrocytes as this cell type produces SZP, and therefore, SZP would be found in the media of the cultured chondrocytes. A person of ordinary skill in the art would have expected success by culturing chondrocytes as these culturing of these cells are well documented in the art and immortalized chondrocytes are readily available. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

5. Applicant argues that the teaching of Rosenberg is not relevant art as the megakaryocyte stimulating factor disclosed in Rosenberg is not the same as the megakaryocyte stimulating factor described by the specification as SZP. A review of the literature and a search through the Human Gene Nomenclature Committee indicates that there is only one MSF, which is also known as JCAP, SZP and PRG4. Thus, Applicant's arguments have been fully considered but they are not persuasive.

6. Claims 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg (US 4,894,440) in view of Turner *et al.* (US 2002/0137894 A1). Rosenberg teaches MSF purified to homogeneity (7.5.times.10.sup.5 -fold) from serum-free conditioned medium obtained from cultured human embryonic kidney (HEK) cells. Rosenberg also teaches the isolation of the MSF DNA and insertion into a phage expression vector. As a matter of fact, MSF is referenced in the art as SZP and proteoglycan 4 (see for example, Ikegawa *et al.* (IDS)).

Rosenburg does not expressly teach the exogenous expression of MSF in cultured cells (regarding claims 11-19), but suggests that MSF may be produced in genetically engineered organisms, or modified MSF may be produced with altered activity.

Turner *et al.* teach the family of MSFs. Turner *et al.* teach recombinant or genetically engineered MSFs for intracellular expression in a bacterial host, such as *E. coli* (section [0045]). The MSF proteins and the DNA sequences encoding MSFs of Turner *et al.* can be produced via recombinant genetic engineering techniques and purified from a mammalian cell line which has been designed to secrete or express the MSF to enable large quantity production of pure, active

MSFs useful for therapeutic applications. The proteins may also be expressed in bacterial cells, e.g., *E. coli*, and purified therefrom. SZP purified from *E. coli* would not be glycosylated. The proteins may also be expressed and purified in yeast cells or in baculovirus or insect cells (see section [0107]).

Taken together, the above reference teaches the method of claims 11-19. It would have been obvious to the person of ordinary skill in the art at the time the invention was made to recombinantly express MSF or SZP for the purposes of purification. The person of ordinary skill in the art would have expected success a purification of a secreted protein from the media of cultured cells is well documented in the art. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

7. Applicant argues that the teaching of Rosenberg is not relevant art as the megakaryocyte stimulating factor disclosed in Rosenberg is not the same as the megakaryocyte stimulating factor described by the specification as SZP. A review of the literature and a search through the Human Gene Nomenclature Committee indicates that there is only one MSF, which is also known as JCAP, SZP and PRG4. Furthermore, the MSF activity described by Rosenberg is associated with the activity of MSF. Thus, Applicant's arguments have been fully considered but they are not persuasive.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

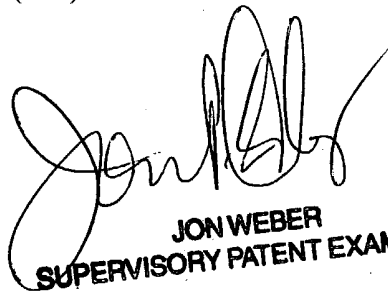
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (571) 272-0959. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
November 19, 2004

SKS


JON WEBER
SUPERVISORY PATENT EXAMINER